

REMARKS

After entry of this Amendment, the pending claims are: claims 1, 2, 4-8, 10, 15, 16, 18, 22-25, 27, 31-38. The Office Action dated February 4, 2008 has been carefully considered. Claims 9 and 11-14 were previously canceled. Claims 3, 17, 19-21, 26 and 28-30 are currently canceled without prejudice. Claims 1, 5, 7, 15, and 24 have been amended. Claims 33-38 have been added. Support for the amendments to claims 1, 15 and 24 and for the addition of claims 33-38 can be found throughout the Specification and Drawings and specifically in paragraph Nos. 120-128 and drawing Nos. 36A-40B. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated February 4, 2008, the Examiner rejected claims 1-8, 10 and 15-32 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,986,771 to Paul *et al.* ("Paul") in view of U.S. Patent No. 7,097,648 to Globerman *et al.* ("Globerman").

INDEPENDENT CLAIM 1

Independent claim 1 has been rejected as being unpatentable over Paul in view of Globerman. As amended, independent claim 1 recites, *inter alia*, a flexible connection unit comprising a longitudinal rod having an outer surface, including a first end, a second end, and a center section wherein the center section includes a plurality of grooves along at least a portion of the outer surface of the center section and a plurality of holes formed in the center section of the rod, each hole intersecting one of the grooves formed in the outer surface of the rod.

Paul discloses a hollow circular tube or rod incorporating one or more helical spiral slits cut along at least a portion of the tube. As admitted by the Examiner, Paul does not disclose, teach or suggest a plurality of holes formed in the center section of the rod wherein each hole intersects one of

the grooves formed in the outer surface of the rod. Rather, the Examiner relies upon Globerman to disclose a plurality of holes formed in the rod.

Globerman discloses an expandable intervertebral spacer wherein, in an unexpanded configuration, the intervertebral spacer 20 is in the form of an elongated hollow object 22, such as a tube, having a plurality of spikes 24 defined thereon (in a flattened form), each spike 24 being defined by a pair of slots 26. In an expanded configuration, the tube 22 is axially compressed so that the flattened plurality of spikes 24 can extend outward so that a considerable expansion in the diameter of the intervertebral spacer 20 is achieved while simultaneously a considerable reduction in the axial length of the intervertebral spacer 20 is achieved. The slots 26 may include one or more holes 32 to reduce the propagation of stress and/or mechanical failure in the hollow tube 22. The holes 32 also weaken the ends of the slots 26 so that when the intervertebral spacer 20 is axially collapsed, the spikes 24 will preferentially fold out at the ends of the slots 26 at the holes 32.

According to the Examiner, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the rod disclosed in Paul with holes as taught by Globerman in order to arrive at the claimed invention.

Applicants respectfully disagree. It is respectfully submitted that one of ordinary skill in the art would not combine the expandable intervertebral spacer of Globerman with the spirally grooved longitudinal spinal rod of Paul. Generally speaking, the longitudinal spinal rod disclosed in Paul is used to interconnect two or more vertebrae bodies in order to secure the position of one vertebra with respect to the other vertebra while still enabling the spinal rod to bend. Globerman is directed to an expandable

intervertebral spacer wherein the intervertebral spacer includes an elongated unexpanded configuration so that the intervertebral spacer can be inserted into the intervertebral disc space through a relatively small opening. Once implanted, the ends of the intervertebral spacer are contracted or compressed causing the intervertebral spacer to collapse upon itself so that while the axial length of the intervertebral spacer is decreased, the diameter of the intervertebral spacer is increased in order to fill the intervertebral disc space.

It is respectfully submitted that one of ordinary skill in the art would not look to combine holes formed in an intervertebral spacer in order to facilitate the axial collapsing and diametrical expansion of an expandable intervertebral spacer with a longitudinal spinal rod configured to secure the relative positions of adjacent vertebrae. It is respectfully submitted that the Applicants through their own effort and expense derived the device as claimed in independent claim 1. It is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign the longitudinal, spirally wound spinal rod of Paul to incorporate a plurality of holes such that the holes intersect the spiral grooves. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. _____ (2007) ("[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does."

Therefore, it is respectfully submitted that contrary to the Examiner's assertion, it would not be obvious for one of ordinary skill in the art to construct the rod disclosed in Paul with holes as taught by Globerman in order to arrive at the invention of independent claim 1. Thus, it is respectfully submitted

that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2, 4-8 and 10 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2, 4-8 and 10 is also respectfully requested.

INDEPENDENT CLAIMS 15 AND 24

Independent claims 15 and 24 were rejected as being unpatentable over Paul in view of Globerman. As amended, independent claims 15 and 24 both recite, *inter alia*, a longitudinal solid metal rod having an outer surface, including: a first end, a second end and a substantially cylindrical center section located between and coupled to the first end and the second end, the center section including a plurality of grooves formed in the outer surface of the rod and a plurality of tunnels formed in the center section of the rod, each tunnel including a pair of openings located on opposite sides of the outer surface of the rod, wherein the tunnel openings intersect the grooves formed in the outer surface of the rod.

Paul discloses a hollow circular tube or rod incorporating one or more helical spiral slits cut along at least a portion of the tube. As admitted by the Examiner, Paul does not disclose, teach or suggest a plurality of tunnels formed in the center section of the rod wherein each tunnel includes a pair of diametrically opposed openings on the outer surface of the rod, the tunnel openings intersecting the grooves formed in the outer surface of the rod.

Globerman discloses an expandable intervertebral spacer wherein, in an unexpanded configuration, the intervertebral spacer 20 is in the form of an elongated hollow object 22, such as a tube, having a plurality of spikes 24 defined thereon (in a flattened form), each spike 24 being defined by a pair of slots 26. In an expanded configuration, the tube 22 is axially compressed so that the flattened plurality of spikes 24 can extend outward so that a considerable expansion in the diameter of the intervertebral spacer 20 is achieved while simultaneously a considerable reduction in the axial length of the intervertebral spacer 20 is achieved. The slots 26 may include holes 32 to reduce the propagation of stress and/or mechanical failure in the tube 22. These holes 32 also weaken the end of the slots 26 so that when the intervertebral spacer 20 is axially collapsed, the spikes 24 will preferentially fold out at the ends of the slots 26 at the holes 32.

According to the Examiner, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the rod disclosed in Paul with holes as taught by Globerman in order to arrive at the claimed invention.

Assuming *arguendo* that the combination of Paul and Globerman is proper, which in our opinion and judgment it is not, the combination still would not disclose, teach or suggest each and every limitation of amended independent claims 15 and 24. In particular, amended independent claims 15 and 24 require that the longitudinal rod be in a solid metal rod having a substantially cylindrical center section. It is respectfully submitted that both Paul and Globerman disclose a hollow tube.

Moreover, independent claims 15 and 24 recite, *inter alia*, a plurality of tunnels formed in the solid metal center section of the rod, each tunnel including a pair of openings diametrically opposed on

opposite sides of the outer surface of the rod. It is respectfully submitted that since both Paul and Globerman disclose hollow tubes, they can not disclose, teach or suggest a plurality of tunnels formed in the center section of the rod, each tunnel including a pair of openings diametrically opposed on opposite sides of the outer surface of the rod. Furthermore it is respectfully submitted that Paul and Globerman can not disclose, teach or suggest the tunnel openings intersecting the grooves formed in the outer surface of the rod.

Therefore, it is respectfully submitted that neither Paul and/or Globerman, either alone or in combination, disclose, teach, or suggest all of the limitations of independent claims 15 and 24. Thus, it is respectfully submitted that independent claims 15 and 24 are allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claims 15 and 24 is respectfully requested.

Furthermore, as claims 16, 18, 22 and 23 all depend from independent claim 15, and claims 25, 27, and 31-38 all depend from independent claim 24, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 16, 18, 22, 23, 25, 27 and 31-38 is also respectfully requested.

CONCLUSION

A fee of \$810.00 is believed due for this submission for the filing of the Request for Continued Examination. The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

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In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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